Citation:

Alonso A, Beunza JJ, Bes-Rastrollo M, Pajares RM, Martínez-González MA. Vegetable protein and fiber from cereal are inversely associated with the risk of hypertension in a Spanish cohort. *Arch Med Res*. 2006 Aug; 37 (6): 778-786.

PubMed ID: 16824939

Study Design:

Prospective cohort study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To assess the role of different nutritional factors, especially protein and fiber from different sources, on the risk of incident hypertension in a cohort of Spanish university graduates.

Inclusion Criteria:

Graduate of the University of Navarra (Spain) or a member of certain selected Spanish professional associations.

Exclusion Criteria:

- Participants who reported a diagnosis of cancer, cardiovascular disease or diabetes at the beginning of the follow-up or were prevalent cases of hypertension
- Participants missing values for any of the variables considered in the analysis or with implausible or extreme caloric intakes (less than 400kcal or more than 3,500kcal per day for women and less than 600 or more than 4,200kcal per day for men).

Description of Study Protocol:

Recruitment

From December 1999 through January 2002, an explanatory letter and a mailed questionnaire were sent to former students of the University of Navarra and to memebers of some Spanish professional associations.

Design

Prospective cohort.

Dietary Intake/Dietary Assessment Methodology

A semi-quantitative food frequency questionnaire (FFQ) asked the frequency of consumption of 136 items in the previous year.

Statistical Analysis

- Quintiles of nutrient intake were used with the lowest intake as the reference category. Linear trends were assessed by assigning the median value to each quintile and modeling these values as a continuous variable
- Cox proportional hazards models were used to assess the association between nutrient intake and the incidence of hypertension.

Data Collection Summary:

Timing of Measurements

- A baseline questionnaire-assessed diet
- Biennial questionnaires-assessed incident hypertension.

Dependent Variables

Hypertension: Self-reported through questionnaire (asks if the participant has received a medical diagnosis of hypertension).

Independent Variables

- Total, vegetable and animal protein intake daily
- Total daily carbohydrate intake
- Total daily fat intake (saturated, polyunsaturated, monounsaturated)
- Total daily fiber intake (fiber from fruit sources, fiber from vegetable sources).

Control Variables

- Total energy intake
- Age
- Sex
- Body mass index (BMI)
- Physical activity
- Smoking
- Alcohol consumption
- Sodium intake
- Personal history of hypercholesterolemia
- Other dietary factors (fruit, vegetables, low-fat dairy, potassium, magnesium, fiber, caffeine, saturated fatty acids and monounsaturated fatty acids).

Description of Actual Data Sample:

- *Initial N:* 6,686 (after study exclusions)
- *Attrition (final N):* 5,880 (3,604 female and 2,276 male)
- *Age:* Mean (standard deviation):
    - 33.8 (9.8) years for females

- 38.9 (11.5) years for males
- *Other relevant demographics:* University graduates, 48% health professionals
- *Anthropometrics:* Mean (SD) for BMI:
  - 21.8 (2.8)kg/m^2 for females
  - 25.1 (2.9)kg/m^2 for males
- *Location:* Spain.

Summary of Results:

Key Findings

- Total carbohydrates, glycemic load, protein and fat intake and intakes of different types of fat were not associated with the risk of hypertension when adjusted for multiple potential confounders
- Protein from vegetable sources, but not total or animal protein, was inversely associated with the risk of hypertension. The hazard ratio of hypertension among those with the highest intake of vegetable protein compared to those with the lowest intake was 0.5 (95% CI: 0.2 to 0.9, P=0.06)
- Total fiber intake and fiber from fruits or vegetables were not associated with the risk of hypertension. Fiber from cereal was inversely associated with the risk of hypertension (hazard ratio for the highest vs. the lowest quintile of intake = 0.6, 95% CI: 0.3 to 1.0, P=0.05).

Other Findings

For both vegetable protein and cereal fiber, the inverse association with hypertension was stronger among older than younger people, among men than women, and only for vegetable protein, among obese or overweight than among lean participants.

Author Conclusion:

Vegetable protein and fiber from cereal were inversely associated with the risk of hypertension.

Reviewer Comments:

Study Strengths

- *The validity of the FFQ was assessed in a Spanish population; self-reported BMI and self-reported leisure-time physical activity had high validity; and self-reported hypertension status had adequate validity*
- *The high level of education in the cohort increased study internal validity and probably improved the quality of self-reported data*
- *The response rate for the participants included in the study was 88%*
- *Characteristics of study participants and those lost to follow-up were compared.*

Study Limitations

- *Hypertension status was self-reported*
- *Diet was evaluated with a single baseline FFQ*
- *Negative results for some associations may have been due to a lack of statistical power*

- *There were some differences between the characteristics of study participants and those lost to follow-up.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A

3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	No
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A

6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	N/A
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes

8.6.	Was clinical significance as well as statistical significance reported?	N/A
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes